

**HL7 SPL Working Group Process Communication Forum Telecon  
Wednesday, Jan 12, 2011**

Check out the SPL Working Group WIKI @:  
<http://spl-work-group.wikispaces.com>

**Questions on SPL:**

ER/DL regulatory questions? Send to [edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov)

SPL technical questions? Send to [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov)

UNII or SRS questions? Send to [fda-srs@fda.hhs.gov](mailto:fda-srs@fda.hhs.gov)

*As of Jan 13, 2011: DailyMed has over 20,000 SPL loaded.*

**Minutes:**

**Meeting schedule for 2011: tel# 1-877-423-2663 PIN# 240184**

Same day of week, different PIN.

**Update from SPL indexing meeting**

- Very well attended and productive meeting. FDA indicated that they'd like to see it continued.
- Attendees from several database companies (companies that aggregate data for further use), clinical decision support (FirstDataBank, GoldStandard), several pharmaceutical companies, some downstream users from Regenstrief and Epic, and eight FDA participants.
- The potential use of SPL data is immense. Importance of accurate and ongoing maintenance of data. FDA needs to be clear about downstream uses when they create the indexing data.
- SPL Indexing needs to be looked at across products. The downstream databases use a paradigm (information being searched, conceptualized, grouped) different from paper PI (a more linear reading of documents)
- Recommendations on the order of approaching indexing: Boxed Warnings -> Pregnancy Information -> Indications
- FDA has prepared established pharmacologic class [EPC] information for existing products. These files are available for review at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162549.htm>
  - All Pharmacologic Class indexing files have been prepared for upload by NLM. NLM is making plans to display the data contained in the Pharmacologic Class SPL.
  - Right now, FDA planning only to provide as SPL files.

- Database developers would like to see the established pharmacologic class data available in tabular format. Currently, FDA plans to make it available in xml format, with NLM providing the display area.

**ISSUE: We all benefit from current, complete prescribing information out on Daily Med**

- For maximal use of data out on DailyMed, how do we reach those folks that are not compliant with the regulation and supporting guidances?  
This lack of availability in DailyMed raises concerns with Paperless Labeling initiative as well.
- Consumers & HCPs contact the FDA about out-of-date labels on DailyMed.  
Embarrassing for the FDA and... likely an embarrassment for sponsors as well.

How is this being addressed by FDA?

1. Example: Medguide updates now go through a validation check. Older labels (R3 format, some R4 already out on DailyMed) haven't passed through that validation check, but are still out there with missing or incorrect LOINC codes.
2. FDA (in early – mid 2010) reviewed SPLs that were over 1 year old, and contacted the companies out of compliance.
  - a. Some companies complied. Some companies are out of business.
  - b. Data is getting better
  - c. FDA will continue to do this to make sure that data is current.
3. Approval letters now contain statement of requirement to submit SPL via eList.  
Approval letters posted on Drugs@FDA and sent to sponsor  
Snail Mail (hard copy sent via US Postal Service) - letter sometimes received long after the cover letter sent.

**RECOMMENDATION:** Request by pharma to FDA that approval letters should be sent electronically instead of by snail mail. Snail mail seems to be getting more prevalent than in the past. Thus a big part of the 14 days is gone before industry gets the approval via snail mail.

[FDA representation was not aware that sponsors were not always being notified promptly. Will take this observation back to Review Division]

Office of Generics way of working – practice is to fax the approval letter, then follow with paper copy. SPL is required before approval of the application. Timeliness of the approval comes into play (patent expiration rapidly approaching)

4. FDA can follow up with companies out of compliance with the 14 day filing of SPL via eList to troubleshoot, remind and/or assist sponsors.

**SUGGESTION:** If the 14-day timeline can't be met, contact the FDA via letter of explanation. For instance, communicate that the SPL is in progress. Haven't had

negative feedback from the FDA. [*Thanks to Dragan Obradovich for this suggestion!*]

5. Remaining R3 labeling on DailyMed

FDA is not planning to remove the label since the FDA doesn't want to make a mistake in removing the wrong label. FDA spent 2-3 years fixing setids because mistakes were made. The FDA does not want the responsibility of manually fixing/removing files. NLM does not want to remove a file

**RECOMMENDATION:**

*To delist an old product that only has an R3 label, you only need to add application data, market start and end date to the R3 xml.*

*Include image that says 'no image provided' [create your own or find one by searching for 'no image available jpg' on the Internet.*

*You don't have to provide a copy of the label, don't need to provide the manufacturing information.*

- SPL Indexing sub-team will be kicked off in the near future. Ed Millikan (ASHP) will be leading this effort.

**Big thank you to Pam B for pulling together the SPL Indexing meeting in December**

## **Discussion on SPL Medication Guide - Generic Drug SPL Documents**

- FDA receives a report each month of all products out on DailyMed that do not have their Medication Guide correctly coded.
- Most of the incorrectly coded Medication Guides are appearing in Generic medications SPL. If the Medication Guide is incorrectly coded or missing, strictly speaking the SPL is incomplete. [most of these files were posted before the medication guide validation rule].
- *FDA will be following up with those companies with missing or incorrectly coded Medication Guides.*

## **OTC / ER-DL Update**

- Late last year (2010):  
**Huascar Batista** (FDA Office of Compliance) and **Lonnie Smith** (FDA Data Standards Council) participated on an SPL **OTC sub-team call late last year**. They addressed questions related to imports drug registration and listing issues. Notes are available

on the WIKI at <http://spl-work-group.wikispaces.com/file/view/SPL+OTC+Sub-team+13+December+121510.pdf>

- ER/DL subteam had some questions that they wanted to discuss further with DRLS meeting. Paul Loebach has graciously agreed to meet with the subteam in the next couple months for another Q&A session.
- Request for questions to be extended to OTC group. Invites for participation to be extended to Charise Kasser. (CVM), Vada Perkins (CBER), and others from FDA interested in the Q&A.
- Drugs for further processing – Pragmatics Lite validator now updated to check for this marketing category [*Thanks to Howard Schatz of DCL for checking on this!*].

## General updates

- Previously: SPL group at FDA has been loading SPL manually if an establishment in the SPL has not yet sent in their DER electronically.
- In the future: FDA will probably not load these any longer because the establishment is now out of compliance.
- FDA had a huge number of validation errors for Registration files that had an effective date of 2011 (but were sent in end-Dec-2010).
- If you send a drug listing file and it includes an establishment that has not yet electronically registered, you are likely to get back this error e-mail:

Greetings,

Drug establishments are required to be registered annually on or before December 31st. Content of labeling/listing SPL documents which, in the establishment data elements section, include information for drug establishments that are not registered electronically **may** no longer be manually loaded. Registrants of drug establishments have had from June 1, 2009, to December 31, 2010, to electronically register their drug establishments.

***RECOMMENDATION: File establishment registrations as early as possible in 2011.***

## Other Questions / Issues

- Image difficulties: <http://spl-work-group.wikispaces.com/Images> . If you need more assistance, contact [SPL@fda.hhs.gov](mailto:SPL@fda.hhs.gov). We'll post any other tips and advice on image provision on the WIKI.
- Postings of SPL to web repository  
<http://www.accessdata.fda.gov/spl/data/rootID/rootID.xml> will soon be under 48 hours. If your file seems not to be accessible at this location, send a note to [SPL@fda.hhs.gov](mailto:SPL@fda.hhs.gov) with the rootid. Ask that the file be activated.

Next meeting scheduled for:

**Wednesday, Jan 26, 2011**

**Time: 1:00-2:30 ET**

**Dial-in info: number 1-877-423-2663 PIN# 240184**

- Minutes of previous Process Team meetings are here:  
<http://spl-work-group.wikispaces.com/Process+Communications+Forum>